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JAN 1 1 1995

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Re: Patent Term Extension #19
Application for
U.S. Patent No. 4,621,077

ORDER TO SHOW CAUSE

This is in response to the request for patent term extension, filed November 21, 1995. The application states that the approved product FOSAMAX is claimed in U.S. Patent No. 4,621,077 because when FOSOMAX is administered, it breaks down in the patient's body into the claimed drug.

35 U.S.C. § 156 states:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if- . . . .
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use; . . .
>
> (f) For the purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of-
> (A) a new drug, antibiotic drug, . . . as those terms are used by the Federal Food, Drug, and Cosmetic Act. . . including any salt or ester or the active ingredient . . . .

Accordingly, one requirement of the statute is that the patent must claim the approved product or a method of using or manufacturing the product. Applicant's patent, U.S. Patent No. 4,621,077, claims: "A method of ... administering to a patient in need thereof an effective amount of 4-amino-1-hydroxybutane 1, 1-biphosphonic acid." However, the active ingredient of the approved product, FOSOMAX, is aledronate sodium or 4-amino-1-hydroxybutane 1, 1-biphosphonic acid monosodium salt trihydrate. The two compounds are not the same, and 4-amino-1-hydroxybutane 1, 1-biphosphonic acid is neither a salt nor an ester of the active ingredient, i.e. aledronate sodium, of the approved drug product. Therefore, the claims of the patent that encompass the use of 4-amino-1-hydroxybutane 1, 1-biphosphonic acid do not encompass the use of FOSOMAX, the approved product.

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To be eligible for patent term extension, the patent must claim an active ingredient of the approved product or the method of use or manufacturing of the active ingredient. 35 U.S.C. § 156(f)(2)(A). "[A]n 'ingredient' must be present in the drug product when administered." Glaxo Operations Uk Ltd. v. Quigg, 706 F. Supp. 1224,1227-28, 10 USPQ2d 1100,1103 (E.D. Va. 1989), aff'd 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990). The drug 4-amino-1-hydroxybutane 1, 1-biphosphonic acid is not an ingredient of FOSOMAX, the approved product. The drug 4-amino-1-hydroxybutane 1, 1-biphosphonic acid is not present in FOSOMAX and thus is not present when that drug product is administered. Accordingly, 4-amino-1-hydroxybutane 1, 1-biphosphonic acid cannot be an active ingredient as defined by the statute.

Applicant is given a non-extendable time limit of TWO MONTHS to give a reasoned explanation as to why the patent is considered to claim an active ingredient of the approved product.

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